

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS  
(Boston Division)**

**BRIAN RAFFERTY,**

**Plaintiff,**

**V.**

**MERCK & CO., INC. and  
SIDNEY RUBENSTEIN,**

**Defendants.**

**CIVIL ACTION NO: 1:14-CV-10252**

**ANSWER AND DEFENSES TO  
PLAINTIFF'S COMPLAINT**

**JURY TRIAL REQUESTED**

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Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned counsel, submits the following Answer and Defenses to Plaintiff's Complaint ("Complaint"). Any allegations in the Complaint not specifically admitted herein are denied. More specifically, Merck responds to the numbered and unnumbered paragraphs in Plaintiff's Complaint as follows:

With respect to the first unnumbered paragraph in Plaintiff's Complaint, Merck denies the allegations therein and denies that it has any liability to Plaintiff for any of the claims or allegations set forth in the Complaint or the Plaintiff's Statement of Estimated Money Damages attached thereto.

**PARTIES**

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint and, therefore, denies all allegations set forth therein.

2. Merck admits the allegations contained in Paragraph 2 of the Complaint.

3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of the Complaint and, therefore, denies all allegations set forth therein.

**JURISDICTION AND VENUE**

4. Merck denies the allegations contained in Paragraph 4 of the Complaint.

5. Merck states that it lacks knowledge or information sufficient to admit or deny the allegations contained in Paragraph 5 of the Complaint and, therefore, denies them.

6. The allegations contained in Paragraph 6 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Merck states that it lacks knowledge or information sufficient to admit or deny said grounds for venue at this time and, therefore, denies them.

**FACTUAL ALLEGATIONS**

7. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 7 of the Complaint and, therefore, denies all allegations set forth therein.

8. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 8 of the Complaint and, therefore, denies all allegations set forth therein.

9. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 9 of the Complaint and, therefore, denies all allegations set forth therein.

10. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 10 of the Complaint and, therefore, denies all allegations set forth therein.

11. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 11 of the Complaint and, therefore, denies all allegations set forth therein.

12. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 12 of the Complaint and, therefore, denies all allegations set forth therein.

13. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 13 of the Complaint and, therefore, denies all allegations set forth therein.

14. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 14 of the Complaint and, therefore, denies all allegations set forth therein.

15. Merck admits that the FDA approved Proscar for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate subject to the information contained in its FDA-approved prescribing information. Merck respectfully refers the Court to the relevant prescribing information for its full text. Merck further admits that Proscar contains 5 milligrams of finasteride. Except as expressly admitted, Merck denies the allegations contained in Paragraph 15 of the Complaint.

16. Merck admits that it manufactures Proscar and that Proscar contains 5 milligrams of finasteride. Except as expressly admitted, Merck denies the allegations contained in Paragraph 16 of the Complaint.

17. Merck admits that the FDA approved Proscar for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate subject to the information contained in its FDA-approved prescribing information. Merck respectfully refers the Court to the relevant prescribing information for its full text. Except as expressly admitted, Merck denies the allegations contained in Paragraph 17 of the Complaint.

18. Merck admits that the FDA approved Proscar for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate subject to the information contained in its FDA-approved prescribing information. Merck respectfully refers the Court to the relevant prescribing information for its full text, including the information concerning potential side effects. The allegations contained in Paragraph 18 are vague and confusing. Except as expressly admitted, and due to vague and confusing nature of the allegations, Merck denies the allegations contained in Paragraph 18 of Complaint.

19. Merck admits that the FDA approved Proscar for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate subject to the information contained in its FDA-approved prescribing information. Merck respectfully refers the Court to the relevant prescribing information for its full text. Except as expressly admitted, Merck denies the allegations contained in Paragraph 19 of the Complaint.

20. Merck admits that Proscar has been approved in several European countries. Merck respectfully refers the Court to the relevant prescribing information for the full texts. Except as expressly admitted, Merck denies the allegations contained in Paragraph 20 of the Complaint.

21. Merck denies each and every allegation contained in Paragraph 21 of the Complaint, except Merck admits that Propecia has been approved for use in Sweden. Merck respectfully refers the Court to the relevant prescribing information for its full text.

22. Merck denies each and every allegation contained in Paragraph 22 of the Complaint, except Merck admits that Propecia has been approved for use in the United Kingdom. Merck respectfully refers the Court to the relevant prescribing information for its full text.

23. Merck denies each and every allegation contained in Paragraph 22 of the Complaint, except Merck admits that Propecia has been approved for use in Italy. Merck respectfully refers the Court to the relevant prescribing information for its full text.

24. Merck admits that Plaintiff purports to cite to and/or quote from an article and that article is the best evidence of its text and full content. Except as expressly admitted, Merck denies the allegations contained in Paragraph 24 of the Complaint, including the veracity and sources of the article.

25. Merck admits that Plaintiff purports to cite to and/or quote from an article and that article is the best evidence of its text and full content. Except as expressly admitted, Merck denies the allegations contained in Paragraph 25 of the Complaint, including the veracity and sources of the article.

26. Merck admits that Plaintiff purports to cite to and/or quote from an article and that article is the best evidence of its text and full content. Except as expressly admitted, Merck denies the allegations contained in Paragraph 26 of the Complaint, including the veracity and sources of the article.

27. In support of the allegations set forth in Paragraph 27, Plaintiff cites to more than one blog and other websites. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations or the information cited in support of the allegations contained in Paragraph 27 of the Complaint and, therefore, denies the allegations set forth therein.

28. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 28 of the Complaint and, therefore, denies the allegations set forth therein, except to state that at no time has Merck promoted the “off-label” use of Proscar or Propecia.

29. Merck denies each and every allegation contained in Paragraph 29 of the Complaint.

30. The allegations contained in Paragraph 30 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck admits that it appropriately manufactured and sold Proscar, that it has legal duties imposed upon it by law, and that, at all relevant times, Merck complied with all applicable laws and regulations. Merck specifically denies that it breached any of those duties. Except as expressly admitted, Merck denies the allegations contained in Paragraph 30 of the Complaint.

31. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 31 of the Complaint.

32. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 32 of the Complaint.

33. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 33 of the Complaint.

34. Merck admits that Plaintiff purports to state requirements of a statute and that statute is the best evidence of its content and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 34 of the Complaint.

35. Merck admits that Plaintiff purports to state requirements of a statute and that statute is the best evidence of its content and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 35 of the Complaint.

36. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its content and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 36 of the Complaint.

37. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its content and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 37 of the Complaint.

38. Merck admits that Plaintiff purports to state the requirements of a statute and that statute is the best evidence of its content and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 38 of the Complaint.

39. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 39 of the Complaint.

40. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 40 of the Complaint.

41. Merck admits that after a patent on a drug expires, manufacturers may seek to manufacture and sell a generic version of the drug. Except as expressly admitted, Merck denies the allegations contained in Paragraph 41 of the Complaint.

42. Merck admits that a generic drug is required by federal regulation to contain the same active ingredient(s) as the patented, brand-named drug. Except as expressly admitted, Merck denies the allegations contained in Paragraph 42 of the Complaint.

43. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 43 of the Complaint.

44. Merck admits that Plaintiff purports to cite to, quote from, and/or summarize a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 44 of the Complaint.



45. Merck admits that Plaintiff purports to cite to, quote from and/or summarize a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 45 of the Complaint.

46. Merck admits that Plaintiff purports to cite to, quote from and/or summarize a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 46 of the Complaint.

47. Merck admits that Plaintiff purports to cite to, quote from and/or summarize a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 47 of the Complaint.

48. Merck admits that Plaintiff purports to cite to, quote from and/or summarize a statute and that statute is the best evidence of its content and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 48 of the Complaint.

49. Merck admits that Plaintiff purports to cite to and/or quote from a federal regulation and that federal regulation is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 49 of the Complaint.

50. Merck admits that Plaintiff purports to cite to and/or quote from a federal regulation and that federal regulation is the best evidence of its actual text and intent.

Except as expressly admitted, Merck denies the allegations contained in Paragraph 50 of the Complaint.

51. Merck admits that Plaintiff purports to cite to and/or quote from a federal regulation and that federal regulation is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 51 of the Complaint.

52. Merck admits that Plaintiff purports to cite to, quote from and/or summarize a statute and/or federal regulation and that statute and/or regulation is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 52 of the Complaint.

53. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 53 of the Complaint.

54. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 54 of the Complaint.

55. Merck admits that Plaintiff purports to cite to and/or quote from a federal regulation and that federal regulation is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 55 of the Complaint.

56. Merck admits that Plaintiff purports to cite to and/or quote from a federal regulation and that federal regulation is the best evidence of its actual text and intent.

Except as expressly admitted, Merck denies the allegations contained in Paragraph 56 of the Complaint.

57. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 57 of the Complaint.

58. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 58 of the Complaint.

59. Merck admits that Plaintiff purports to cite to and/or quote from a statute and that statute is the best evidence of its actual text and intent. Except as expressly admitted, Merck denies the allegations contained in Paragraph 59 of the Complaint.

60. The allegations contained in Paragraph 60 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck denies the allegations contained in Paragraph 60 of the Complaint.

61. The allegations contained in Paragraph 61 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck denies the allegations contained in Paragraph 61 of the Complaint.

62. The allegations contained in Paragraph 62 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck admits that it appropriately manufactured and sold Proscar, that it has legal duties imposed upon it by law, and that, at all relevant times, Merck complied with all applicable laws and regulations. Except as expressly admitted, Merck denies the allegations contained in Paragraph 62 of the Complaint.

63. The allegations contained in Paragraph 63 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck admits that it appropriately manufactured and sold Proscar, that it has legal duties imposed upon it by law, and that, at all relevant times, Merck complied with all applicable laws and regulations. Except as expressly admitted, Merck denies the allegations contained in Paragraph 63 of the Complaint.

**RESPONSE TO  
COUNT ONE  
Negligence and Failure to Warn  
(Defendant Merck)**

64. Merck incorporates herein by reference its previous answers to each paragraph set forth herein above.

65. Merck denies each and every allegation contained in Paragraph 65 of the Complaint.

66. Merck denies each and every allegation contained in Paragraph 66 of the Complaint.

67. Merck denies each and every allegation contained in Paragraph 67 of the Complaint.

68. Merck denies each and every allegation contained in Paragraph 68 of the Complaint.

69. The allegations contained in Paragraph 69 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck admits that it appropriately manufactured and sold Proscar, that it has legal duties imposed upon it by law, and that, at all relevant times, Merck complied with all applicable laws and regulations. Merck specifically denies that it breached any of those

duties. Except as expressly admitted, Merck denies each and every allegation contained in Paragraph 69 of the Complaint.

70. The allegations contained in Paragraph 70 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, Merck admits that it appropriately manufactured and sold Proscar, that it has legal duties imposed upon it by law, and that, at all relevant times, Merck complied with all applicable laws and regulations. Merck specifically denies that it breached any of those duties. Except as expressly admitted, Merck denies each and every allegation contained in Paragraph 70 of the Complaint.

71. Merck denies each and every allegation contained in Paragraph 71 of the Complaint.

**RESPONSE TO  
COUNT TWO  
Violation of M.G.L. c. 93A §9  
(Defendant Merck)**

72. Merck incorporates herein by reference its previous answers to each paragraph set forth herein above.

73. Merck admits that Plaintiff's counsel sent it a letter dated March 11, 2013. Merck further admits that it responded to Plaintiff's counsel's letter. Except as expressly admitted, Merck denies the allegations contained in Paragraph 73 of the Complaint.

74. Merck denies each and every allegation contained in Paragraph 74 of the Complaint.

75. Merck denies each and every allegation contained in Paragraph 75 of the Complaint.

76. Merck denies each and every allegation contained in Paragraph 76 of the Complaint.

77. Merck denies each and every allegation contained in Paragraph 77 of the Complaint.

**RESPONSE TO  
COUNT THREE  
Negligence (Failure to Obtain Informed Consent)  
(Defendant Rubenstein)**

78. Merck incorporates herein by reference its previous answers to each paragraph set forth herein above.

79. The allegations contained in Paragraph 79 of the Complaint are not directed at Merck and, therefore, no response is required. To the extent a response is deemed required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 79 of the Complaint and, therefore, denies them.

80. The allegations contained in Paragraph 80 of the Complaint are not directed at Merck and, therefore, no response is required. To the extent a response is deemed required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 80 of the Complaint and, therefore, denies them.

81. The allegations contained in Paragraph 81 of the Complaint are not directed at Merck and, therefore, no response is required. To the extent a response is deemed required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 81 of the Complaint and, therefore, denies them.

82. The allegations contained in Paragraph 82 of the Complaint are not directed at Merck and, therefore, no response is required. To the extent a response is deemed required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 82 of the Complaint and, therefore, denies them.

83. The allegations contained in Paragraph 83 of the Complaint are not directed at Merck and, therefore, no response is required. To the extent a response is deemed required, Merck denies the allegations contained in Paragraph 83 of the Complaint.

84. The allegations contained in Paragraph 84 of the Complaint are not directed at Merck and, therefore, no response is required. To the extent a response is deemed required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 84 of the Complaint and, therefore, denies them.

The final un-numbered paragraph of the Complaint beginning "WHEREFORE" and following Paragraph 84 of the Complaint is not an allegation, and, therefore, no responsive pleading is required. Should a response be deemed required, Merck admits only that Plaintiff purports to demand judgment and certain forms of relief, but Merck denies there is any legal or factual basis for awarding the same. Except as expressly admitted, Merck denies the allegations set forth in the final un-numbered paragraph of the Complaint beginning "WHEREFORE" and following Paragraph 84 of the Complaint, including all subparts 1 through 3.

## **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following defenses should be available to Merck in this matter. Merck, therefore, asserts the following defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer and Defenses to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Without assuming any burden of pleading or proof that would otherwise rest on Plaintiff, Merck states as follows:

### **FIRST DEFENSE**

The Complaint fails to state, in whole or in part, a claim upon which relief can be granted. Merck reserves the right to move to dismiss the Complaint on this and other bases.

### **SECOND DEFENSE**

Each and every claim asserted or raised in the Complaint may be time barred, in whole or in part, by the applicable statute of limitations or statute of repose and/or may be otherwise untimely.

### **THIRD DEFENSE**

This case may be more appropriately brought in a different venue, specifically the Multidistrict Litigation proceeding No. 233 titled *In Re: Propecia (Finasteride) Products Liability Litigation* pending in the Eastern District of New York for federal personal injury/product liability actions involving claims that use of PROPECIA® and/or



PROSCAR® (finasteride) causes persistent sexual dysfunction in a subset of men who took the drug, even after they discontinued its use.

#### **FOURTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other independent, unforeseeable, superseding or intervening cause or causes.

#### **FIFTH DEFENSE**

PROPECIA® and/or PROSCAR® have been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and regulations promulgated thereunder. Therefore, Plaintiff's claims predicated on state tort law are barred, in whole or in part, by the doctrine of federal preemption, the Supremacy Clause of the United States Constitution, Article IV, clause 2, and applicable federal law.

#### **SIXTH DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of PROPECIA® and/or PROSCAR®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to prescribing physicians. To the extent that New Jersey law is found to apply, Plaintiff's claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warnings to prescribing physicians.

#### **SEVENTH DEFENSE**

Plaintiff's claims are barred because the injuries allegedly sustained by Plaintiff were not proximately caused by any act or omission of Merck. Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced pursuant to applicable state law.

#### **EIGHTH DEFENSE**

The injuries and damages, if any, sustained by Plaintiff resulted in whole or in part from his own culpable conduct, intentional acts, contributory or comparative negligence, assumption of risk, and want of care. Accordingly, any damages recovered should be reduced and/or barred in accordance with the applicable law

#### **NINTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer. Pursuant to the doctrines of assumption of the risk and/or informed consent, this conduct bars, in whole or in part, the damages that Plaintiff seeks to recover herein.

#### **TENTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the acts and omissions (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more persons or entities over whom Merck exercises no control and for whom Merck is not legally responsible, including, without limitation, the Plaintiff, and for whom Merck may not be held accountable.

#### **ELEVENTH DEFENSE**

If Plaintiff was injured by any product manufactured, sold, or distributed by Merck, to the extent those injuries occurred because the product was used for a purpose other than that for which it was intended, in a manner other than that in which it was intended to be used, and/or in disregard of instructions and direction regarding its use, such misuse was not reasonably foreseeable to Merck and Plaintiff's damages should be reduced in whole or in part.

#### **TWELFTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from conditions, illnesses, and/or reactions unrelated to the use of the subject product or products, including, but not limited to, Plaintiff's pre-existing and/or unrelated: medical, genetic, and/or environmental conditions; diseases; illnesses; allergic, idiosyncratic, or idiopathic reactions; subsequent medical conditions; and/or natural courses of conditions. Merck is not responsible for any injuries or losses resulting from such pre-existing and/or unrelated conditions, illnesses, and/or reactions.

#### **THIRTEENTH DEFENSE**

Merck neither made nor breached any express warranties, implied warranties, and/or any warranties created by law. To the extent that Plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between Plaintiff and Merck, and/or by Plaintiff's failure to give Merck timely notice of the alleged breach of warranty. Merck further specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code and/or applicable state law.

#### **FOURTEENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because PROPECIA® and/or PROSCAR® were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

#### **FIFTEENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Proscar was made in accordance with the state of the art at the time it was manufactured.

#### **SIXTEENTH DEFENSE**

Plaintiff's claims are barred in whole or in part under comment *k* to Section 402A of the Restatement (Second) of Torts.

#### **SEVENTEENTH DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of PROPECIA® and/or PROSCAR® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment *j* to Section 402A of the Restatement (Second) of Torts.

#### **EIGHTEENTH DEFENSE**

Plaintiff's claims are barred under Sections 2, 4, 6(c), 6(d) and comment *f* to Section 6, of the Restatement (Third) of Torts: Products Liability.

**NINETEENTH DEFENSE**

Plaintiff's claims are barred because the methods, standards, and techniques utilized by Merck in manufacturing, distributing, marketing, or labeling the subject products and in issuing warnings and instructions with respect to their use, were proper and conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drugs were manufactured and distributed. Further, PROPECIA® and/or PROSCAR® was safe for their respective normal and foreseeable uses at all times, not unreasonably dangerous or defective, and their benefits exceeded any associated risks.

**TWENTIETH DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended respective functions of PROPECIA® and/or PROSCAR®.

**TWENTY-FIRST DEFENSE**

Plaintiff's claims are barred, in whole or in part, by his failure to prevent or mitigate damages.

**TWENTY-SECOND DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**TWENTY-THIRD DEFENSE**

With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments *j* and *k* to Section 402A of the Restatement (Second) of Torts relegate Plaintiff's claims to a negligence cause of action.

**TWENTY-FOURTH DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the products involved were unsafe, which Merck denies, then they were unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the products exceeded any apparent risk given the scientific knowledge available when the products were marketed.

**TWENTY-FIFTH DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution and the Constitutions of the Commonwealth of Massachusetts, the State of New Jersey and/or any other applicable state(s).

**TWENTY-SIXTH DEFENSE**

The public interest in the benefit and availability of the products which are the subject matter of this action precludes liability, if any, resulting from any activities undertaken by Merck, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is

determined there exists a risk inherent in the subject products, then such risk, if any, is outweighed by the benefit of the product.

**TWENTY-SEVENTH DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**TWENTY-EIGHTH DEFENSE**

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

**TWENTY-NINTH DEFENSE**

To the extent there were any risks associated with the use of the products which are the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state law.

**THIRTIETH DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**THIRTY-FIRST DEFENSE**

Plaintiff has not suffered any actual injury or damages.

**THIRTY-SECOND DEFENSE**

Plaintiff's claims are barred under the doctrine of economic loss.

**THIRTY-THIRD DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

**THIRTY-FOURTH DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Final Rule, Requirements on content and format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**THIRTY-FIFTH DEFENSE**

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including PROPECIA® and/or PROSCAR®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

**THIRTY-SIXTH DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

**THIRTY-SEVENTH DEFENSE**

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiff.



**THIRTY-EIGHTH DEFENSE**

To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**THIRTY-NINTH DEFENSE**

To the extent that Plaintiff is seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under applicable Massachusetts law, to the extent Massachusetts law applies, or under N.J.S.A. 2A:15-97, to the extent that New Jersey law applies.

**FORTIETH DEFENSE**

Merck is not guilty of negligence and violated no duty owing to Plaintiff.

**FORTY-FIRST DEFENSE**

The extent of any risk associated with the use of PROPECIA® and/or PROSCAR®, the existence of which is not admitted, was, at the time of the distribution of said product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

**FORTY-SECOND DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, *res judicata*, payment, and/or release.

**FORTY-THIRD DEFENSE**

Plaintiff's damages, if any, are barred or reduced by the doctrine of avoidable consequences.

**FORTY-FOURTH DEFENSE**

Plaintiff is barred from recovery and/or Plaintiff's recovery is limited by M.G.L.A. 231 § 85, to the extent that Massachusetts law applies, and by the New Jersey Comparative Negligence Act, N.J.S.A. 2A:15-5.1, *et seq.*, to the extent that New Jersey law applies.

**FORTY-FIFTH DEFENSE**

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiff, then it shall only be liable for its equitable share of Plaintiff's recovery since any liability which would be found against it will be insufficient to impose joint liability. Merck's liability, if any, is limited by the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, *et seq.*, to the extent New Jersey law applies, and by M.G.L.A. 231B §§ 1 & 3, to the extent that Massachusetts law applies.

**FORTY-SIXTH DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

**FORTY-SEVENTH DEFENSE**

To the extent that New Jersey law applies to Plaintiff's claims, Merck affirmatively pleads all defenses available to it pursuant to N.J.S.A. 2A:58C-1, *et seq.*, otherwise known as the New Jersey Product Liability Act.

**FORTY-EIGHTH DEFENSE**

To the extent that New Jersey law applies to Plaintiff's claims, those claims are confined to those available under the New Jersey Product Liability Act.

**FORTY-NINTH DEFENSE**

This case may be subject to dismissal or stay on the grounds of *forum non conveniens*.

**FIFTIETH DEFENSE**

The claims of the Plaintiff may be barred, in whole or in part, from recovery because he has made statements or taken actions that preclude him from asserting claims or constitute waiver of his claims.

**FIFTY-FIRST DEFENSE**

Plaintiff's claims are barred because Merck complied with all applicable state and federal statutes regarding the product in question, including the requirements and regulations promulgated by the U.S. Food and Drug Administration and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged by the Complaint. PROPECIA® and/or PROSCAR® were reasonably fit, suitable, and safe for their respective intended uses. In the event that Plaintiff's claims are not barred, Merck is entitled to a presumption that the products in question are free from any defect or defective condition as the plans or design for the products or the methods and techniques of manufacturing, inspecting, and testing the products were in conformity with government standards established for the prescription drug industry that were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting, and testing the product were adopted.

**FIFTY-SECOND DEFENSE**

Plaintiff received all or substantially all of the benefit from the subject products that Plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from Merck must be correspondingly reduced.

**FIFTY-THIRD DEFENSE**

To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Merck's rights under the United States Constitution.

**FIFTY-FOURTH DEFENSE**

Plaintiff's claims of fraud are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Federal Rule of Civil Procedure 9(b).

**FIFTY-FIFTH DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**FIFTY-SIXTH DEFENSE**

To the extent that Plaintiff seeks punitive damages, such claims are barred because PROPECIA® and/or PROSCAR® and its respective labeling were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTY-SEVENTH DEFENSE**

With respect to Plaintiff's demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as set forth in *BMW of North America v. Gore*, 116 U.S. 1589 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 531 U.S. 923 (2001), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and, to the extent Massachusetts law applies, *Flesner v. Technical Communications Group*, 575 N.E.2d 1107 (Mass. 1991).

**FIFTY-EIGHTH DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award, if granted, would violate Merck's state and federal constitutional rights.

**FIFTY-NINTH DEFENSE**

Pursuant to the Excessive Fines Clause of the Eighth Amendment and the Due Process Clauses of the Fifth and Fourteenth Amendment of the United States Constitution, Plaintiff's claim for punitive damages is specifically limited to the amount of any applicable fine which may be imposed on Merck by the government of the United States, the State of New Jersey, the Commonwealth of Massachusetts, and/or any other governmental or quasi-governmental agency, commission, or body.

**SIXTIETH DEFENSE**

Plaintiff's claim for punitive damages is barred by various provisions of the United States Constitution, the New Jersey Constitution, and the Massachusetts Constitution. An award of punitive damages under New Jersey or Massachusetts law

violates Article I, Article III, and the First, Fifth, Sixth, Seventh, Eighth, and Fourteenth Amendments of the United States Constitution, Article I, Paragraph 1 of the New Jersey Constitution, and Part 1, Articles X and XII of the Massachusetts Constitution in various ways, including the following:

- a. the judiciary's ability to correct a punitive damage award only upon a finding of passion, prejudice, or caprice is inconsistent with due process guarantees;
- b. any award of punitive damages serving a compensatory function is inconsistent with due process guarantees;
- c. any award of punitive damages based upon the wealth or financial status of Merck violates due process and equal protection guarantees;
- d. any award of punitive damages would be in violation of the due process clause pursuant to *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), and its progeny;
- e. any award of punitive damages would be a violation of the prohibition against ex post facto laws and laws impairing the obligations of contracts;
- f. the standards and instructions for awarding punitive damages are inadequate, vague, and ambiguous, and, thus, such an award is inconsistent with due process guarantees;
- g. there are no realistic standards or limits imposed on the amount of punitive damages which may be awarded and no required relationship between the actual damages sustained and the amount of punitive damages which may be awarded, and, thus, such an award is inconsistent with due process guarantees;
- h. the jury's unfettered power to award punitive damages in any amount it chooses is wholly devoid of meaningful standards and is inconsistent with due process guarantees;
- i. the vague standards employed in punitive damage cases results in extremely disparate outcomes among similar defendants accused of similar conduct, and, thus, such an award is inconsistent with due process and equal protection guarantees;
- j. even if it could be argued that the standard governing the imposition of punitive damages exists, the standard is void for vagueness;
- k. the purpose of punitive damages is punishment and deterrence, and there are not adequate procedural safeguards in place to protect Merck's right against self-incrimination, right to proof beyond a reasonable doubt, and right to be free from unreasonable searches and seizures in this case, and, thus, such an award is inconsistent with due process guarantees;
- l. the threat of an award of unlimited punitive damages chills Merck's ability to exercise its right to access to the courts;
- m. any award of punitive damages may violate the proscription against the award of excessive fines; and

- n. any claim for punitive damages may be barred by the “double jeopardy” clause.

#### **SIXTY-FIRST DEFENSE**

The correct standard for submitting the burden of proof for exemplary and/or punitive damages is “clear and convincing” evidence. Any lesser standard is a violation of the Due Process Clause of the Fourteenth Amendment of the United States Constitution.

#### **SIXTY-SECOND DEFENSE**

Merck is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in the Commonwealth of Massachusetts, the State of New Jersey, and/or any other law or statute that may be applicable.

#### **SIXTY-THIRD DEFENSE**

Plaintiff’s causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of PROPECIA® and/or PROSCAR®.

#### **SIXTY-FOURTH DEFENSE**

Plaintiff’s causes of action are barred in whole or in part by his failure to assert a safer design for PROPECIA® and/or PROSCAR®.

#### **SIXTY-FIFTH DEFENSE**

To the extent that Plaintiff seeks to hold Merck liable for failure to warn, which is expressly denied, Merck had no duty to warn Plaintiff of the type of injuries alleged by him.

**SIXTY-SIXTH DEFENSE**

The Plaintiff does not detrimentally rely on any labeling, warnings, or information concerning PROPECIA® and/or PROSCAR®.

**SIXTY-SEVENTH DEFENSE**

To the extent New Jersey law applies, Merck specifically incorporates and asserts all defenses and limitations to punitive damages awards available under N.J.S.A. 2A:15-5.9, *et seq.*

**SIXTY-EIGHTH DEFENSE**

Merck & Co., Inc. is not a proper defendant in this case.

**SIXTY-NINTH DEFENSE**

This case may be more appropriately brought in a different venue.

**SEVENTIETH DEFENSE**

Merck asserts the defenses of insufficient process and insufficient service of process under under Federal Rules of Civil Procedure 12(b)(4) and 12(b)(5).

**SEVENTY-FIRST DEFENSE**

The averments of the Complaint fail to give Merck reasonable notice of facts sufficient to complete the choice of law analysis for the Plaintiff. For that reason, Merck expressly reserves its right to assert further or additional affirmative defenses if it is determined that further or additional affirmative defenses exist under the applicable state law.



**SEVENTY-SECOND DEFENSE**

The averments of the Complaint fail to give Merck reasonable notice of facts sufficient to evaluate all of its defenses. For that reason, Merck affirmatively pleads improper venue, arbitration, release, assumption of risk, statute of limitations, discharge in bankruptcy, fraud, illegality, res judicata, statute of frauds, estoppels, laches, waiver and any other matter constituting an avoidance of affirmative defense that is available to Plaintiff.

**DEMAND FOR JURY TRIAL**

Merck specifically requests and demands a trial by jury as to all issues so triable.

WHEREFORE, PREMISES CONSIDERED, Merck requests that Plaintiff's Complaint be dismissed with prejudice with all costs and fees assessed against Plaintiff along with such other relief that the Court may deem just and proper.

DATED this 3rd day of February, 2014.

Respectfully submitted,

/s/ William L. Parker

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*Attorneys for Defendant Merck & Co., Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused the foregoing to be electronically filed with the Clerk of the Court using the ECF system which sent notification of such filing to all registered attorneys including:

Emily E. Smith Lee  
Sana Abdullah  
Beth M. Nussbaum  
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Sharon, MA 02067

**ATTORNEYS FOR PLAINTIFF**

SO CERTIFIED 3<sup>rd</sup> day of February, 2014.

/s/ William L. Parker

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William L. Parker